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Sequenom Supreme Court Patent Eligibility Challenge

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§ 9[f] Rethinking *Sequenom* at the Supreme Court : A Fresh Approach

Sequenom, Inc. v. Ariosa Diagnostics, Inc., is the styling of the expected *certiorari* petition from *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, __ F.3d __ (Fed. Cir. Dec. 2, 2015)(Order denying en banc review), *panel proceedings*, 788 F.3d 1371 (Fed. Cir. 2015). This section takes a fresh approach to the issues in the case and how the case *should* be considered at the Supreme Court:

An appellate tribunal quite naturally looks at an appeal from the standpoint of the arguments presented by the appellant in its opening brief. After all, the burden rests with the appellant to show why the decision below is wrong. In this way, the patentee in *Ariosa* at the Federal Circuit let the court fall into the trap of a step by step analysis focusing neither on the invention *as a whole* nor on the principal basis for the denial of patent-eligibility in the *Bilski* through *Alice* line of case law, that granting certain patents "preempts" future research and use of particular subject matter. *Bilski* v. *Kappos*, 561 U.S. 593 (2010)(software); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)(diagnostic method); the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics., Inc.*, 133 S. Ct. 2107, 2116 (2013)(DNA, *per se*); *Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014)(software).

A fresh approach is needed. The issue should be framed in the following manner:

Where an invention is to a method to *detect* the existence of particular DNA in the fetal bloodstream through the nonobvious choice to draw blood from the arm of the mother (instead of prior art womb-invasive amniocentesis), does the fact that the object of the testing is the recognition of *known* and hence unpatentable DNA, does the fact that DNA, *per se*, may lack patent-eligibility deny patent-eligibility of the DNA testing method, particularly where there is absolutely no "preemption" of the use of fetal DNA in any way, shape or form?

§ 9[f][1] Consideration of the Invention *as a Whole*

The Federal Circuit decision fails to look to the invention *as a whole*, a requirement explained in the *Adams Battery* case:

"While the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly, *Burns v. Meyer*, 100 U.S. 671, 672 (1880); *McCarty v. Lehigh Valley R. Co*., 160 U.S. 110, 116 (1895), it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention, *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 547 (1871); *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 312 U.S. 654 (1940); *Schering Corp. v. Gilbert*, 153 F.2d 428 (2nd Cir. 1946)."

§ 4[a], *The Invention "As a Whole"* (quoting the *Adams Battery* case, *United States v. Adams*, 383 U.S. 39, 48-49 (1966); *see also id.* (citing *Prouty v. Draper*, 41 U.S. (16 Pet.) 335 (1842); *Vance v. Campbell*, 66 U.S. (1 Black) 427, 429 (1861); *Water-Meter Co. v. Desper*, 101 U.S. (11 Otto) 332, 337 (1879); *White v. Dunbar*, 119 U.S. 47 (1886).

§ 9[f][2] A "Microscope" to *Identify* Previously Known DNA

The better approach is to view the invention in the coming *Sequenom* petition *as a whole* whereupon one sees an invention which can be compared to a "microscope", a "ruler", a "laser detection device"… or a simple blood test performed in a doctor's office to see whether a subject has a particular disease or other abnormality. The instant invention is most comparable to a simple blood test drawn from the arm. There are undoubtedly thousands of improvements which have been made over the last century in conventional blood testing and none has been subject to the absurd notion that it lacks patent-eligibility under 35 USC § 101. In the context of this case, all of the "microscope"-like inventions have in common the *measurement* or *identification* of some DNA or other matter found in

a bodily fluid. The *measured* or *identified* substance is the object of the testing, but that object is not in any way patented through use of the "microscope" nor is that object's use for future research blocked by the test of the "microscope".

In the invention of the *Sequenom* petition, the claimed invention *as a whole* provides a test of a pregnant mother's *blood sample* drawn from the arm, just as one runs any conventional blood test in a doctor's office. But, this is not like any other blood test, one that is a fabulous breakthrough because the prior art had no conception that this blood test could be operative to test for fetal DNA. First of all, there was no recognition that fetal DNA was present in the maternal blood stream: Indeed, the amount of such fetal DNA in the bloodstream was *de minimis* in terms that there is not enough of the substance to permit its identification. Secondly, coupled with the recognition by the inventors that there *is* a trace amount of fetal DNA in the bloodstream, the invention includes the recognition that this trace amount of DNA could be *amplified* by the surprising breakthrough of Dr. Cary Mullis' Nobel Prize-winning polymerase chain reaction (PCR) technology. While one could consider, *arguendo*, that the application of Mullis' technology would have been obvious had this occurred immediately after his Nobel Prize-winning discovery, a generation went by after his discovery until the present invention was created.

§ 9[f][3] Breakthrough Technology that is, *a Fortiori*, "Inventive"

There can be no doubt in any way, shape or form about the breakthrough nature of the instant invention: Imagine, to permit a fetal DNA test which involves drawing blood from a pregnant mother's arm *versus* the conventional prior art method of womb-invasive amniocentesis to extract fluid from the womb! Without a doubt, the invention in this case is a true breakthrough and, *a fortiori,* one that is manifestly nonobvious under 35 USC § 103. *See* § 9[c], *"Inventive" Subject Matter under the "All Elements" Rule.*

§ 9[f][4] There is No "Preemption" Issue in this Case

Tthere is absolutely zero preemption of any kind concerning the object of the blood test in this case: The only object of prenatal testing is to *identify* the presence or absence of certain known DNA. There is no patent protection for any such DNA as to the DNA, *per se*, nor to its use or to its manufacture. Zero.

But, "preemption" is the basic ground to deny patent-eligibility of categories of inventions as explained in detail in § 3[b], *"Research Preemption" Confusion in Mayo.* As stated in that section, *Mayo* quite clearly pins denial of patent-eligibility to "preemption":

> [U]pholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.
>
> * * *
>
> * * * [D]o the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?
>
> * * *

The Court has repeatedly emphasized *** a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.

* * *

In *Bilski* the Court pointed out that to allow "petitioners to patent risk hedging would preempt use of this approach in all fields."

* * *

[T]]here is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify.

* * *

[The claims] threaten to inhibit the development of more refined treatment recommendations ***.

* * *

The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible[.].

* * *

[The patentee] encourages us to draw distinctions among laws of nature based on whether or not they will interfere significantly with innovation in other fields now or in the future.

But the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor. A patent upon a narrow law of nature may not inhibit future research as seriously as would a patent upon Einstein's law of relativity, but the creative value of the discovery is also considerably smaller. And, as we have previously pointed out, even a narrow law of nature (such as the one before us) can inhibit future research.

In any event, our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow. And this is understandable. Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building-block" concern. [citations omitted]

Mayo (citations omitted)

Later cases reprise the *Mayo* preemption theme. *See* § 3[b], *"Research Preemption" Confusion in Mayo* (quoting the *Myriad* case, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc*., 133 S. Ct. 2107 (2013), and *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014)).

In terms of the policy arguments behind the denial of patent-eligibility in the case law from *Bilski* to *Alice* the constant drumbeat is one of "preemption", that grant of a patent to an invention will "preempt" research or use of, for example, the DNA discovered in *Myriad.*

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